K001534

JUN 1 2 2000

DePuy
a Johnson-Johnson company

## SUMMARY OF SAFETY AND EFFECTIVENESS

DePuy Orthopaedics, Inc.
PO Box 988
700 Orthopaedic Drive
Warsaw, Indiana 46581-0988
USA
Tel: +1 (219) 267 8143
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|---|---|
| **NAME OF FIRM:** | DePuy Orthopaedics, Inc.<br>P.O. Box 988<br>700 Orthopaedic Drive<br>Warsaw, IN 46581-0988 |
| **510(k) CONTACT:** | Lynnette Whitaker<br>Manager, Regulatory Affairs |
| **TRADE NAME:** | Pinnacle Acetabular System |
| **COMMON NAME:** | Acetabular Cup Prosthesis |
| **CLASSIFICATION:** | 888.3358 Hip joint metal/polymer semi-constrained cementless prosthesis |
| **DEVICE PRODUCT CODE:** | 87 LPH |
| **SUBSTANTIALLY EQUIVALENT DEVICES:** | Pinnacle Acetabular System |

**DEVICE DESCRIPTION AND INTENDED USE:**
The Pinnacle Acetabular System is indicated for total hip replacement in the following conditions:

1. A severely painful and/or disabled joint from osteoarthritis, traumatic arthritis, rheumatoid arthritis, or congenital hip dysplasia.
2. Avascular necrosis of the femoral head.
3. Acute traumatic fracture of the femoral head or neck.
4. Failed previous hip surgery including joint reconstruction, internal fixation, arthrodesis, hemiarthroplasty, surface replacement arthroplasty, or total hip replacement.
5. Certain cases of ankylosis.

All Pinnacle porous-coated acetabular shells are indicated for cementless application.

The Pinnacle Acetabular System is part of a modular system for use in total hip replacement. The acetabular component is provided as two separate units, a porous coated hemispherical outer shell manufactured from titanium alloy (Ti-6Al-4V) and a liner manufactured from ultra high molecular weight polyetheylene (UHMWPE), which locks into the outer shell. The liner component articulates with a femoral head of an appropriate diameter.

**BASIS OF SUBSTANTIAL EQUIVALENCE:**
The Pinnacle Acetabular System has the following similarities to the acetabular cup liners that were cleared in K000306: same intended use; same material; same method of manufacture; same design; same sterilization and packaging methods. The Pinnacle Acetabular System demonstrated adequate performance in design control activities.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 12 2000

Ms. Lynnette Whitaker
Group Leader, Regulatory Affairs
Depuy Orthopedics, Inc.
P.O. Box 988
700 Orthopedic Drive
Warsaw, Indiana 46581-0988

Re: K001534
Trade Name: Pinnacle Acetabular System
Regulatory Class: II
Product Code: LPH
Dated: May 11, 2000
Received: May 17, 2000

Dear Ms. Whitaker:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general control provisions of the Act. The general control provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597, or at its Internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative and
Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known) K001534

Device Name Pinnacle Acetabular System

Indications for Use:

The DePuy Pinnacle Acetabular System is intended to be used to resurface the acetabular socket in cemented or cementless total hip arthroplasty.

The Pinnacle Acetabular System is indicated for total hip replacement in the following conditions:

1. A severely painful and/or disabled joint from osteoarthritis, traumatic arthritis, rheumatoid arthritis, or congenital hip dysplasia.
2. Avascular necrosis of the femoral head.
3. Acute traumatic fracture of the femoral head or neck.
4. Failed previous hip surgery including joint reconstruction, internal fixation, arthrodesis, hemiarthroplasty, surface replacement arthroplasty, or total hip replacement.
5. Certain cases of ankylosis.

All Pinnacle porous-coated acetabular shells are indicated for cementless application.

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Concurrence of CDRH, Office of Device Evaluation

Donna R. Vochmer

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K001534

Prescription Use Yes OR Over-The Counter Use No
(Per 21 CFR 801.109)